DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 21, 2014

Purple Surgical International Limited
Mr. Alan Schwartz
MDI Consultants Incorporated
55 Northern Boulevard, Suite 200, Great Neck
New York, New York 11021

Re: K142868
Trade/Device Name: Laparoscopic Electrodes & Monopolar cables
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 14, 2014
Received: October 23, 2014

Dear Mr. Alan Schwartz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K142868

Device Name: Laparoscopic Electrodes & Monopolar cables

Indications for Use:

The devices are indicated for:

use in general laparoscopic surgery requiring the use of monopolar electrosurgical cutting and/or coagulation.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY

Purple Surgical - Laparoscopic Electrodes & Monopolar cables

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Purple Surgical International Limited.
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Hertfordshire,
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UK

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Facsimile: +44(0) 1923 839444

Contact Person: Jason Howes
Date Prepared: September 2014

Candidate Device details

Proprietary/Trade name: Laparoscopic Electrode with J hook
Laparoscopic Electrode with L hook
Laparoscopic Electrode with Spatula
Monopolar cable with 4mm pin
Monopolar cable with 8mm pin

Common or Usual Name: Laparoscopic Electrode & Monopolar cable

Classification Name: Electrosurgical cutting and coagulation device and accessories, 21 C.F.R. § 878.4400

Device classification: II

Product code: GEI

Classification Panel: General & Plastic surgery

Predicate Device details

Device name / 510k: Monopolar J hook probe 5mm/33cm with cable (k103508)
Monopolar L hook probe 5mm/33cm with cable (k103508)
Monopolar Spatula probe 5mm/33cm with cable (k103508)

Manufacturer: Unimax Medical Systems Inc., Taiwan.

Further to a review of the MAUDE database – The predicate devices listed have not been subject a design related recall.

Device Description

The Laparoscopic Electrodes are electrosurgical devices, used for a variety of laparoscopic procedures through a port, for coagulation and transection of soft tissue and vessels by use of high frequency electric current. The Monopolar cable provides the electrical connection between the Electrode and a suitable electrosurgical generator. Both the Laparoscopic Electrodes and Monopolar cables are single patient use and supplied sterile to healthcare professionals only.

The Laparoscopic Electrodes each consist of a fully insulated, stainless steel shaft, 33cm in length, incorporating three different available types of thermally conductive, insulated metal tip electrodes for conveyance of HF electric current and operated via an ergonomic plastic handle for tactile feedback during surgery procedures. The device should be used through a surgical cannula that has an internal diameter of greater than 5mm.

The Monopolar cable is an insulated copper cord for conveyance of high frequency electrosurgical energy that connects between the HF diathermy connector situated at the end of the handle of the Laparoscopic Electrode and the specified output terminal of a suitable electrosurgical generator (not supplied), with a neutral electrode (not supplied) required to complete the electrosurgery circuit. They are intended for use at a maximum rated voltage of 5.5KVpeak. Coagulation and cutting is achieved using electrosurgical energy supplied via various types of electrosurgical generator.

The associated accessories required to complete the electrosurgical circuit include:

Electrosurgical generator.
Neutral Electrode.

Intended Use / Indications for Use

The Laparoscopic Electrodes & Monopolar cables are used for a variety of laparoscopic procedures through a port, for coagulation and transection of soft tissue and vessels by use of high frequency electric current.

The devices are indicated for:

use in general laparoscopic surgical procedures requiring the use of monopolar electrosurgical cutting and or coagulation.

Comparison of Technological Characteristics with the Predicate Device Substantial Equivalence Determination

Monopolar electrosurgical cutting and coagulation of soft tissue during Laparoscopic surgical procedures is the technological principle for both the candidate and predicate devices.

The candidate and predicate devices are based on the same technological elements:

- Laparoscopic Electrodes 33cm in length & 5mm diameter designed for use through the appropriate surgical trocar ports.
- Three different available electrode tips : L hook, J hook & Spatula
- Stainless steel, insulated shaft assembly.
- Plastic ergonomic handle
- HF diathermy male connector
- Monopolar cable, insulated, copper cored featuring 4mm female connector (for connection to the electrode) and at the opposite end fitted with either a 4mm or 8mm, industry standard, male pin (for connection to the ESU).
- Single use application
- Provided Sterile

The following technological differences exist between the candidate and predicate devices:

- Sterilization method (Gamma Irradiation v Ethylene Oxide)

The Laparoscopic Electrodes & Monopolar cables are as safe and effective as the predicate device and are manufactured by the same company to the same basic specification as the predicate device.

The Purple Surgical Laparoscopic Electrodes & Monopolar cables are substantially equivalent to the in terms of intended use, technological characteristics, principles of operation, materials and performance to cleared Unimax Laparoscopic instrument covered under k103508. Any minor differences in this section do not raise any new issues with respect to safety and effectiveness.

<table>
<tr><td>Item</td><td colspan="3">Candidate device - Purple Surgical - Laparoscopic Electrodes & Monopolar cables</td><td colspan="3">Predicate device – Unimax Medical Systems – Laparoscopic Instrument</td></tr>
<tr><td>Intended use</td><td colspan="3">intended to be used for use in general laparoscopic surgery requiring the use of monopolar electrosurgical cutting and/or coagulation.</td><td colspan="3">use in general laparoscopic surgery requiring the use of monopolar electrosurgical cutting and/or coagulation.</td></tr>
<tr><td rowspan="2">Models / Type / (part code)</td><td colspan="3">5mm Laparoscopic electrode</td><td colspan="3">Monopolar probe</td></tr>
<tr><td>J hook (PS3880)</td><td>L hook (PS3881)</td><td>Spatula (PS3882)</td><td>J hook (FPJ533050)</td><td>L hook (FPL533050)</td><td>Spatula (FPS533050)</td></tr>
<tr><td rowspan="2">Accessories / (part code)</td><td colspan="3">Monopolar cable</td><td colspan="3">Monopolar cable</td></tr>
<tr><td colspan="2">4mm pin (PS3551C4)</td><td>8mm pin (PS3551C8)</td><td colspan="2">4mm pin (FDC232080)</td><td>8mm pin (FDC132080)</td></tr>
<tr><td>Energy type</td><td colspan="3">Monopolar</td><td colspan="3">Monopolar</td></tr>
<tr><td>Dimensions</td><td colspan="3">Shaft Diameter = 5mm
Shaft length = 33cm</td><td colspan="3">Shaft Diameter = 5mm
Shaft length = 33cm</td></tr>
</table>

Sterilization	Radiation	Ethylene oxide

Performance Data

The following performance data was provided in support of the substantial equivalence determination:-

Biocompatibility testing
The biocompatibility evaluation for the Laparoscopic Electrodes was conducted in accordance with International Standard ISO 10993-1 - Biological Evaluation of the Medical Devices, Part 1 – Evaluation and testing in the risk management process as recognized by FDA. The testing included the following testing for

Cytotoxicity
Sensitization
Irritation

The Laparoscopic Electrodes are considered tissue contacting for a duration of less than 24 hours. The Monopolar cables are considered non-patient contacting, therefore testing was deemed unnecessary.

Electrical safety and Electromagnetic compatibility
Electrical safety was conducted on the Laparoscopic Electrodes & Monopolar cables in accordance with IEC60601-2-2 and IEC60601-1 standards. EMC to IEC60601-1-2 standard was not carried out on the basis that High Frequency Surgical equipment are intentional emitters of EMC.

Functionality testing
Functionality testing on the Laparoscopic Electrodes & Monopolar cables was conducted to verify the device's coagulation and transection capabilities in a simulated surgical procedure, using chicken breast as the test model.

Sterility testing
Sterility testing was conducted on the Laparoscopic Electrodes & Monopolar cables in accordance with ISO11137 standard for Gamma Irradiation.

Shelf Life Testing and Packaging Stability
Shelf life testing was conducted to natural aging and accelerated aging in line with ASTMF1980 methodology and ISO11607 for Sterile Packaging requirements, to ensure maintenance of sterility and retained product functionality over time.

Conclusion

The Laparoscopic Electrodes & Monopolar cables are considered as safe and effective as the predicate device and is manufactured to the same basic specification as the predicate device. The Performance data demonstrates that the device is fit for purpose and the results observed were as expected and in accordance with recognized standards.

The Laparoscopic Electrodes & Monopolar cables have the same intended use, indications for use, principles of operation and virtually identical technological characteristics as the predicate device. Due to the similarities, it's considered that the minor differences between the Laparoscopic Electrodes & Monopolar cables and its predicate device do not raise any new issues of safety or effectiveness.

Thus, the Laparoscopic Electrodes & Monopolar cables are considered substantially equivalent to the predicate device.